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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/518,501 03/03/00 ERION

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ART UNIT	PAPER NUMBER
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MCKENZIE, T

DATE MAILED:
1624

06/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/518,501

Applicant(s)

ERION ET AL.

Examiner

Thomas C McKenzie, Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-165 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-165 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to an application filed on 3/3/00. There are one hundred sixty-five claims pending. Claims 1-57, 161, 162, and 165 are compound claims. Claims 58-149, 163, and 164 are use claims. Claims 150-160 are synthesis claims. The application concerns some cyclic phosphate esters and amides and uses thereof.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 17 and 18, drawn to cyclic phosphorus esters, compounds of formula I where one Y = oxygen, classified in class 558, subclass 81.
- II. Claim 19, drawn to cyclic phosphorus amides, compounds of formula I where both y = nitrogen, classified in class 564, subclass 19.
- III. Claims 58-69, drawn to uses of Group I or II compounds for bioavailability, classified in class 514, subclass 110 and 111.
- IV. Claims 70-74, drawn to uses of Group I or II compounds for delivering a drug, classified in class 514, subclass 110 and 111.
- V. Claims 75-83, drawn to uses of Group I or II compounds for drug delivery to the liver, classified in class 514, subclass 110 and 111.

- VI. Claims 84-88, drawn to uses of Group I or II compounds for improving therapeutic index, classified in class 514, subclass 110 and 111.
- VII. Claims 89-96, drawn to uses of Group I or II compounds for kinase resistance, classified in class 514, subclass 110 and 111.
- VIII. Claims 97-105, drawn to uses of Group I or II compounds for cancer treatment, classified in class 514, subclass 110 and 111.
- IX. Claim 106, drawn to drawn to uses of Group I or II compounds for liver fibrosis, classified in class 514, subclasses 110 and 111.
- X. Claims 107 and 108, drawn to uses of Group I or II compounds for hyperlipodemia, classified in class 514, subclass 110 and 111.
- XI. Claim 109, drawn to uses of Group I or II compounds for parasitic infections, classified in class 514, subclasses 110 and 111.
- XII. Claims 110 and 111, drawn to uses of Group I or II compounds for diagnosis, classified in class 514, subclass 110 and 111.
- XIII. Claims 112-120, drawn to uses of Group I or II compounds against viruses, classified in class 514, subclass 110 and 111.
- XIV. Claims 121-125, drawn to uses of Group I or II compounds for drug delivery to target tissues classified in class 514, subclass 110 and 111.

- XV. Claims 126-137, drawn to uses of Group I or II compounds for P450 tumor cells, classified in class 514, subclass 110 and 111.
- XVI. Claims 138-149, drawn to uses of Group I or II compounds for treating tumor cells, classified in class 514, subclass 110 and 111.
- XVII. Claim 163, drawn to uses of Group I or II compounds for delivering to hepatocytes, classified in class 514, subclass 110 and 111.
- XVIII. Claim 164, drawn to uses of Group I or II compounds for enhancing half-life, classified in class 514, subclass 110 and 111.
- XIX. Claims 150-157, drawn to a synthesis of the compounds of Group I and II, classified in class 558, subclass 81 and Class 564, subclass 19.
- XX. Claims 158-160, drawn to a second synthesis of the compounds of Group I and II, classified in class 558, subclass 81 and Class 564, subclass 19.
- XXI. Claim 161, drawn to an phosphite amide intermediate used in the processes of Groups XIX and XX, classified in class 558, subclass 81 and class 564, subclass 19.
- XXII. Claim 162, drawn to a second phosphate amide intermediate used in the processes of Groups XIX and XX, classified in class 558, subclass 81 and class 564, subclass 19.

Claims 1-16, 20-57, and 165 link Groups I and II.

If Applicants select either group I or Group II, then they should also select a single use from Groups III-XVIII and a single synthesis from Group XIX or Group XX.

3. The inventions are distinct, each from the other because of the following reasons: current practice is to examine one process of using and one process of making in addition to compound claims. Inventions I and II have acquired a separate status in the art as shown by their different classification, thus the patent search required for Group I is not co-extensive with that required for Group II. The basic names of these compounds differ, thus the literature search for these various species will be divergent. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

4. Inventions XXI and XXII are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as intermediates for either the process of Group XIX or the process of Group XX and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. The intermediates could also be used for the synthesis of other cyclic phosphate drugs. Should applicant traverse on the ground that the species are not patentably distinct, applicant should

submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

6. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for the Examiner is (703) 746-3152. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mukund Shah can be reached on (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.

Mukund J. Shah

**Mukund Shah
Supervisory Patent Examiner
Art Unit 1624**

TCMcK *TCMcK*
June 15, 2001